K052451

DEC 8 2005

510(k) Summary

1. Submitter:

MPS Acacia
785 Challenger Street
Brea, CA 92821
Tel: 714-257-0470
Fax: 714-257-0513

2. Contact:

Fergie F. Ferguson, RA/QA Manager
MPS Acacia

3. Date prepared: August 29, 2005

4. Device trade name: MedFlo Elastomeric Pump

   Common name: Elastomeric Infusion Pump

5. Predicate device: MedFlo® LI and LI-KVO
   510(k) number: K011117
   Marketed by: MPS Acacia
   785 Challenger Street
   Brea, CA 92821

   Predicate device: MPS Acacia Pain Kit
   510(k) number: K003476
   Marketed by: MPS Acacia
   785 Challenger Street
   Brea, CA 92821

   Predicate device: ON-Q, PainBuster, C-Bloc, Eclipse, Easypump, Homepump
   510(k) number: K020251
   Marketed by: I-Flow Corporation
   20202 Windrow Drive
   Lake Forest, CA 92630

   Predicate device: Accufuser, Accufuser Plus, and Standard Procedure Kit
   510(k) number: K050770
   Marketed by: McKinley Medical, LLC
   4080 Youngfield Street
   Wheat Ridge, CO 80033

6. Description:

The MPS Acacia MedFlo Elastomeric Pump consists of a non-latex elastomeric bladder that is secured onto a plastic mandrel. Secured to the inside of the mandrel is the non-DEHP administration tubing. Secured to the opposite end of the administration tubing is a male luer lock. Standard IV set accessories are integrated in the administration set of the elastomeric pump and may include (dependant on application as determined by the clinician) an air eliminating filter, pinch clamp, flow restrictor (fixed or variable), Y-site, checkvalve, and bolus mechanism. At the inlet port of the mandrel is a one-way checkvalve to allow for the filling of the device while not allowing fluid backup. Encasing the bladder, mandrel and part of the administration tubing is a clear, protective body. The elastomeric pump does not have an alarm function, is non-DEHP and does not contain latex.

The MPS Acacia MedFlo Elastomeric Pump will be available in configurations consisting of 50 to 500ml fill volume, and 0.5 to 10ml per hour flow rates.

K052451

A procedure kit may consist of an introducer, tear-away sheath, multi-port catheter, syringe, sterile tape, wound dressing, and sterile gloves (dependent on application as determined by the clinician), and may be included with each MedFlo Elastomeric Pump or sold separately dependent on the clinician's requirements.

7. Intended Use:

7.1 The MPS Acacia MedFlo Elastomeric Pump is indicated for continuous and/or intermittent infusion of medications for general infusion use, including antibiotic delivery, chemotherapy, and pain management. Routes of administration include intravenous, intra-arterial, subcutaneous, intramuscular, and epidural. The keep vein open (KVO) version provides a sufficient flow rate to maintain a patient IV line open (i.e. keep vein open). The MedFlo Elastomeric pump may also include an optional Y-site at the distal end of the administration set to allow piggyback infusions, and an optional bolus mechanism intended for patient controlled infusion.

7.2 The MPS Acacia MedFlo Elastomeric Pump is also indicated for continuous and/or intermittent delivery of medication, such as local anesthetics or narcotics, to surgical wound sites and/or close proximity to nerves for preoperative, perioperative, and postoperative regional anesthesia and pain management. Routes of administration include intraoperative, perineural, and percutaneous.

7.3 The MPS Acacia MedFlo Elastomeric Pump is also indicated to significantly decrease narcotic use and pain when used to deliver local anesthetics to surgical wound sites or close proximity to nerves when compared with narcotic only pain management.

7.4 The MPS Acacia MedFlo Elastomeric Pump is disposable and single use only.

8. Technological comparison to predicate device:

The MPS Acacia MedFlo Elastomeric Pump offers the same technique, usage parameters and intended use to the predicate devices. The elastomeric membrane delivers fluid at a controlled rate and manner the same as the predicate devices.

9. Non-clinical test summary:

All components used in the MPS Acacia MedFlo Elastomeric Pump are the same as the components used in the predicate devices from MPS Acacia, 510(k) numbers K003476, and K011117.

10. Conclusion:

The MPS Acacia MedFlo Elastomeric Pump is substantially equivalent to the products currently being legally marketed by MPS Acacia, I-Flow Corporation, and McKinley Medical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 8 2005

Mr. Fergie F. Ferguson
Manager
MPS Acacia
785 Challenger Street
Brea, California 92821

Re: K052451
Trade/Device Name: MedFlo, MedFlo Pain Kit, MedFlo Nerve Block, MedFlo LI and MedFlo-Li-KVO
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: September 6, 2005
Received: September 13, 2005

Dear Mr. Ferguson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

Applicant: MPS Acacia

510(k) NUMBER (IF KNOWN): K052451

DEVICE NAME: MedFlo, MedFlo Pain Kit, MedFlo Nerve Block, MedFlo LI and MedFlo LI-KVO

INDICATIONS FOR USE:

1. The MPS Acacia MedFlo Elastomeric Pump is indicated for continuous and/or intermittent infusion of medications for general infusion use, including antibiotic delivery, chemotherapy, and pain management. Routes of administration include intravenous, intra-arterial, subcutaneous, intramuscular, and epidural. The keep vein open (KVO) version provides a sufficient flow rate to maintain a patient IV line open (i.e. keep vein open). The MedFlo Elastomeric pump may also include an optional Y-site at the distal end of the administration set to allow piggyback infusions, and an optional bolus mechanism intended for patient controlled infusion.

2. The MPS Acacia MedFlo Elastomeric Pump is also indicated for continuous and/or intermittent delivery of medication, such as local anesthetics or narcotics, to surgical wound sites and/or close proximity to nerves for preoperative, perioperative, and postoperative regional anesthesia and pain management. Routes of administration include intraoperative, perineural, and percutaneous.

3. The MPS Acacia MedFlo Elastomeric Pump is also indicated to significantly decrease narcotic use and pain when used to deliver local anesthetics to surgical wound sites or close proximity to nerves when compared with narcotic only pain management.

4. The MPS Acacia MedFlo Elastomeric Pump is disposable and single use only.

Prescription Use XX (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter-Use ____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Scott Cr... 12/6/05

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K052451

Page 1 of 1